NoteBookMaker®

USER MANUAL v 10.0

Training-NoteBook

NoteBook
OPEN
TOC
LIBRARY
HELP
CLOSE Book
EXIT App.

LABORATORY   NOTEBOOK

Company Name	CHEMICALS - R US, INC. 1313 MOCKINGBIRD LANE
Current User	Albert Einstein
Current User Access	Author & Witness
NoteBook Host Server	Macbookpro17 (2)
File Size (MB)	3.4
Account Name	User

NoteBookMaker® Version 10.0R1 2009   -   Un-Registered - CLICK HERE to Register

100 | Browse

Table of Contents

Welcome and thank you for selecting
Note**Book****Maker**® - The World Leader in Electronic Laboratory NoteBooks.

NoteBookMaker™ is a legal notebook system for laboratory professionals. The solution was produced with FileMaker® Developer database software. It is simple to use and manage. Unlike other database solutions, this product delivers true "what you see is what you get", a key feature for legal defense and support for 21CFR Part 11compliance.

NoteBookMaker™ can be setup in single user, multi-user (pier to pier, or client/server). The multi-user mode requires the purchase of FileMaker Pro 7.0 or greater and is best hosted by FileMaker Pro Server. Minimal IT knowledge is required to get started.

It contains 2 main database files a NoteBook, and a Librarian file. The NoteBook file is where the scientist enters their data. The Librarian is where the IT department or administrator sets up users via Library Cards. The NoteBook file looks like a book but has the power of a modern database engine. One can easily create, search, and print scientific data. It uses 2 layouts: Layout 1 text only, and Layout 2 for text and graphics (pictures, sounds and movies).

The direction tool bar controls navigation. Use of the bar controls the correct viewing and printing of data. It was necessary to develop this direction tool bar in order to properly select the correct layout. The record browser is a good visual tool to guide the user through the notebook and list of Cards in the Library

Printing will automatically select the appropriate layout. Data that is ready for patent submission can easily be imaged to pdf, or as a stand-alone data file (similar to this solution) that requires no additional software.   This is critical for 21CFR Part 11 compliance.

The default font is Times New Roman - True Type (12 point). It was selected for its legibility both on screen and on paper. The font face is used in all fields accept the graphics field on layout 2. The graphics field can take a paste from any clipboard compatible program. Sophisticated scans, tables, sound, and movies can be placed. Both layouts have a text field for scientific data. Because this solution works like paper and not just a database, it is limited to how many lines of data that can be displayed in an 8.5 x 11 format. In order to provide the legal aspects of an electronic notebook, some pull down menus were stripped of their normal FileMaker Pro functionality.   Button commands were substituted for the pull down menus to provide specific access & control for the end user and the IT department. Help files are located on the tabs of each layout:

Edit Print Go To Legal

Edit COPY PASTE CUT CLEAR UNDO SPELL

Tool Tips are available for each button and field label. They can be turned off after the user is familiar with the software.

Video Tutorial Support

This manual is supported by QuickTime videos that can be found by going to http://notebookmaker.com. We recommend watching the Note**Book**Maker® tutorial videos to fill in any questions that you may have. The videos can easily be included into a company's standard operating procedure training requirements. A list of vides can be found on the next page. More videos will be added over time, so visit the site periodically.

I

nstallation The program is easy to set up and use. We kept it simple so that it would work as designed, like a laboratory notebook. So let's get started.

The installation program **NoteBookMakerInstaller** will prompt you to install the application and to read the **license agreement**. Installation will default to the program folder directory on the hard drive, and will also place an icon on your desktop. On a Mac, look inside your applications folder and drag it to your dock for easy access.

The installation process will install the NoteBookMaker 10.x application, 10 NoteBooks, a Training-NoteBook, & a Template-NoteBook. On the PC, there are an additional 30 minor files, and on the Mac there is an extension folder. All the files are in the same directory of the program folder. See the section at the end for a complete listing of all files installed. Because only one directory is installed, backup & archiving is a snap. See the sections on backup & archiving strategies.
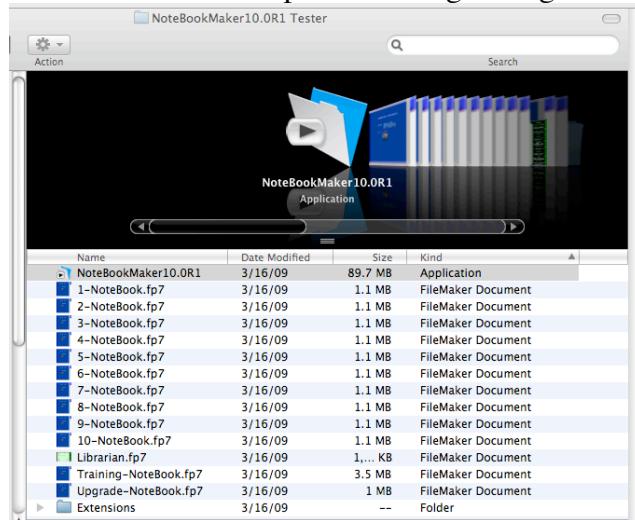

Directory view of the NoteBookMaker installation. Mac version is shown.
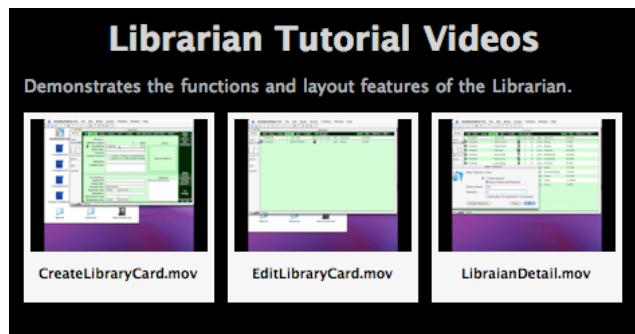
A list of Training videos demonstrating best practice approaches.

Videos require QuickTime Pro Player.

Learn how to create a Library Card, Edit a card, and manage users and notebooks.
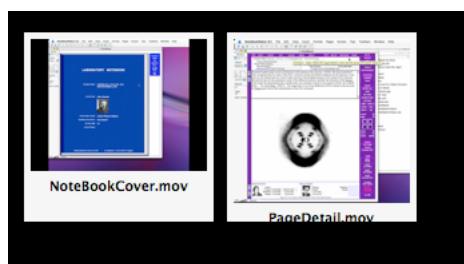
A quick tour of the notebook cover and page.

U sing the Software

Before we can begin entering data into our 1-Notebook, we **must** setup the Librarian with a user and a witness. This is a formal process for each user.

Note: If you are using the demonstration software then you can skip this section for now. Simply open the 1-NoteBookMaker.fp7 file and when prompted, type in **Albert Einstein** for the User and **emc2** for the password. This will log you in as Albert Einstein. Latter you can go to the Card View in the Library and create your own card. When you are ready to purchase a full license then follow the steps below to gain access to the Librarian.

User Set-Up (The Librarian)

Typically, the Librarian is a person who manages the system but they may also be a user as an author, witness or validator . In the single user version, the user is also the Librarian. The Librarian will administer the notebooks and Library Cards.

First, we must open the Librarian data file. If this is your first attempt, you will see 9 Cards for the Training-NoteBook. You can use their ID to explore the functions of the NoteBook system.

Simply click the corresponding NoteBook ID,

and when prompted, type in the user name and password, such as Albert Einstein, emc2.

Now that you have familiarized yourself with the NoteBook, you may want to create a Card for your specific ID. To do this you will need to access the Card layout.

If you have made cards before and want to edit or create new ones, then click the "Create or Edit Cards" button to gain access to the Card layout:

The system comes with the Librarian in Demo Mode, and thus you will not need to type in the administrative user name and password. However, once the Librarian has been registered, then you will need to type in the Librarian user name and password. The registration license is sent via email at time of purchase. Registering the Librarian secures access to the Card layout where all passwords are stored.

For the sake of discussion, let us assume you are in Demo Mode and you have access to the Card layout so you can administer the card system and get familiar with managing the users for the author, witness and validator roles. Once you click the Create or Edit Cards button, a Registration dialog is presented. Select Demo as shown below.
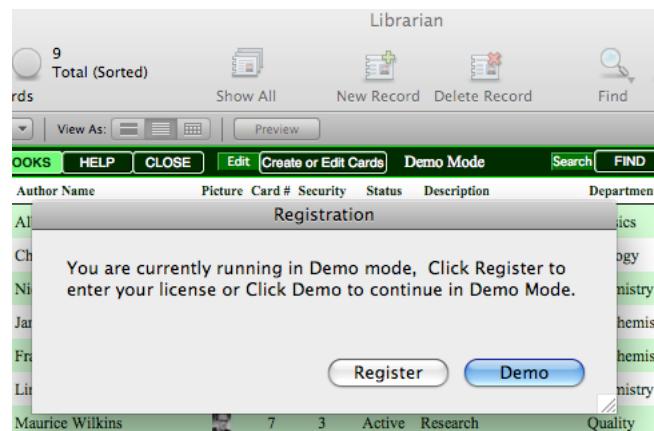
Once clicked, the Card layout is displayed as shown on the next page.

Each system comes with 9 cards that can be edited or deleted. In this case, we will click the New Card button or just modify an existing card.
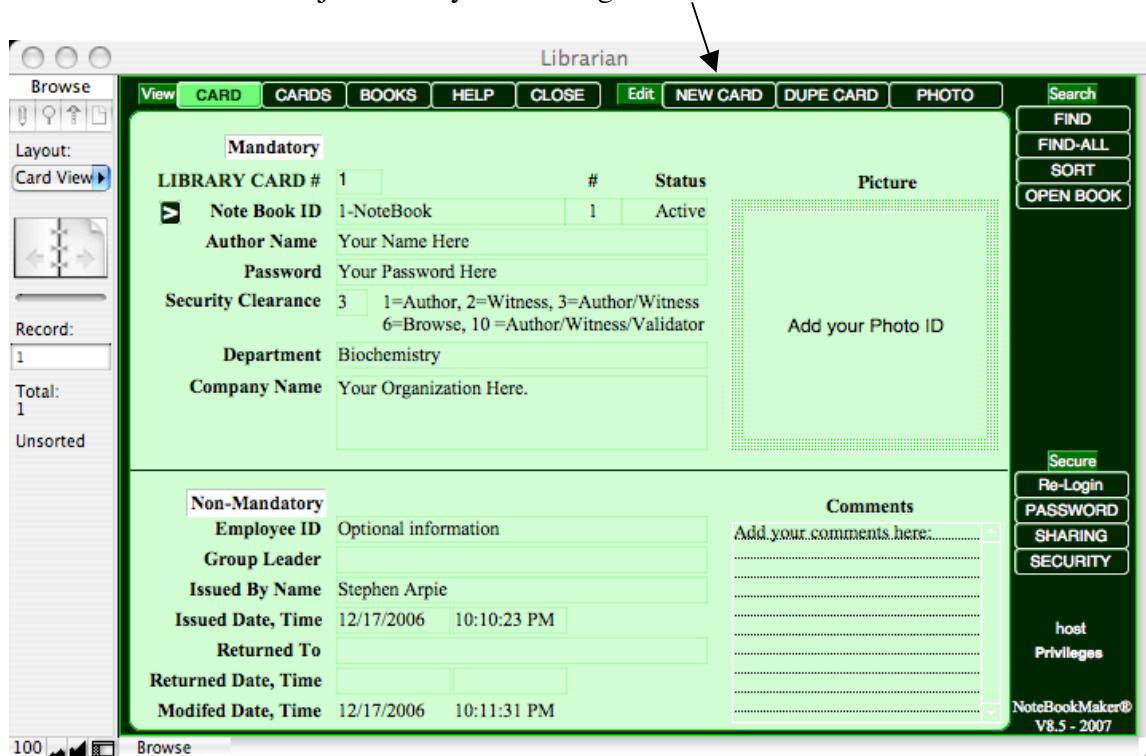
Completely fill out the card for the first user. Include a photo to yield a visual ID of the user. Use a security setting of 3 to allow the new user to witness the first page of the 1-NoteBook. Create a second card for 1-NoteBook that will be used for witnessing. This will be for the person that will review the notebook so here too you will need a security setting of 3. Create as many cards as you have users. It is a good idea to have all your photos and user information before beginning this process. The "host" **Password** should be changed after the system is set-up. See the section on Passwords and Security. Once you have made a Library Card, the user can open a book and login.

In multi-user mode, the Librarian administrator will keep the Librarian.fp7 file open for users to access during their normal login process. It is highly recommended that a dedicated server host the Librarian, and all notebook files. The server should not be used for routine data entry of notebooks, but merely hosting and system administration.

User Login

Now that you have your Card completed, you can open the notebook that it references.

To open the 1-NoteBook, click the > button or the Open Book button.
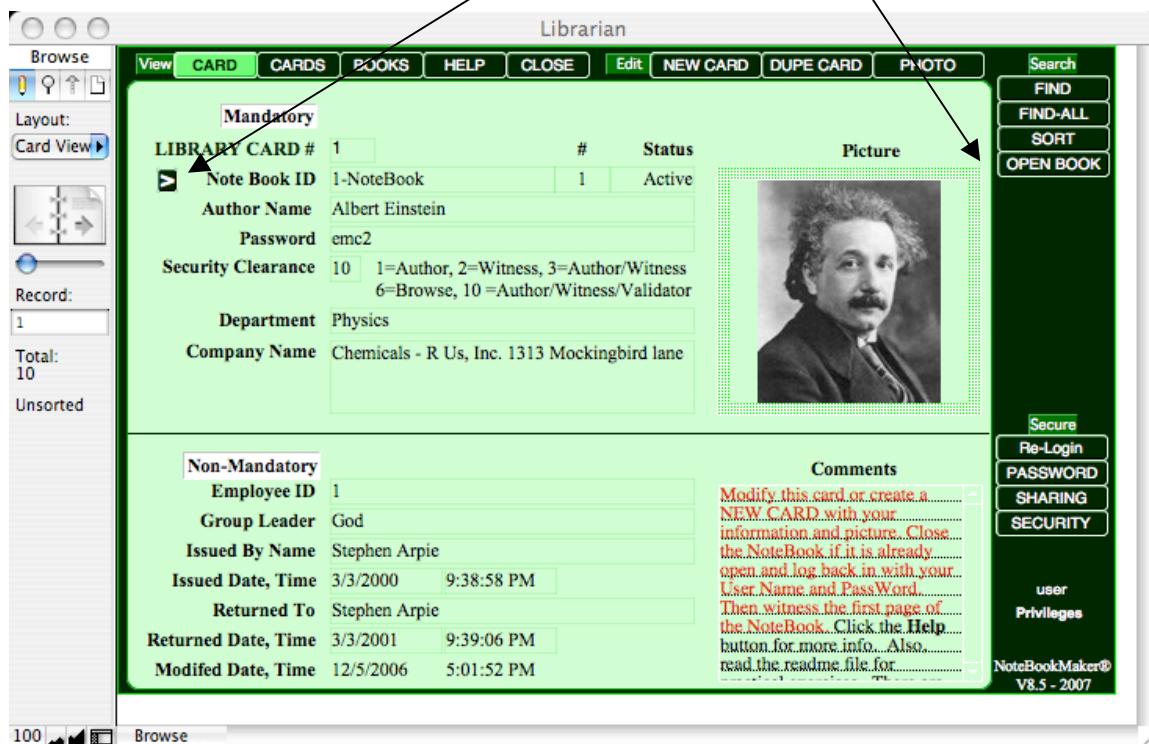
Alternatively, you click out to the Books layout and select as show page 5.
In either event, you will be prompted by this dialog:
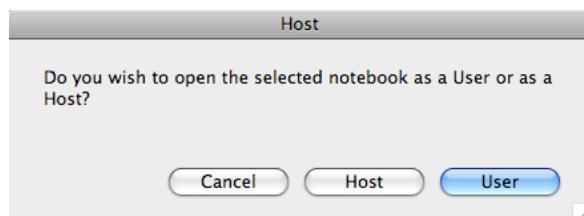
Select User. User access allows for adding pages and content to the notebook system.

The next step will ask for the user name and password that was typed on the card.

When your 1-NoteBook.fp7 file boots up, you will be prompted for:
User Name "your name"
Password "your password"
This is the information that you typed into the Librarian when you set up your card.

Security Log In

User Name and Password

User Name

Your Name Here

Password

****

Cancel   OK
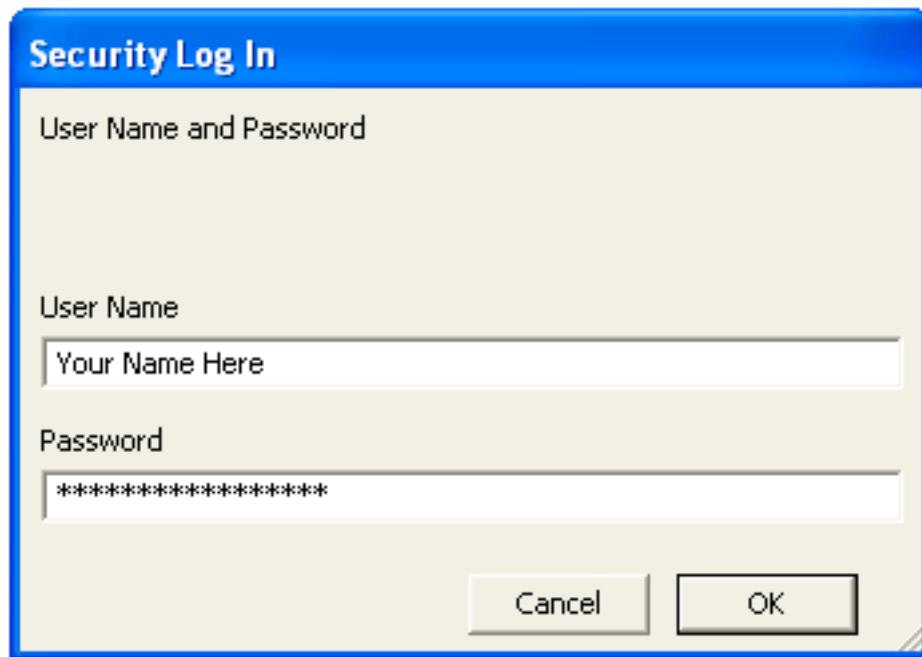
During the login process, the Librarian Security table records the information that the user types. The information typed is compared to the information that was set-up in the Librarian by the administrator/host. If the information is a complete match, then the user is presented with their notebook data file (1-NoteBook.fp7). If the information is not a match, then the user is rejected and has a total of 3 attempts before all the data files are closed.

Upon successful login, the User will appear on the cover as you are presented with your 1-NoteBook (See next section). Their first assignment should be to witness the initial page. This tells management that they have read and understood that this is a secure electronic notebook system.

Click around to get the feel of the application. The user can now start creating and posting pages. On a routine schedule, the person designated as the witness for this 1-NoteBook should review and post their signature to completed pages. The witness will need a Library Card with a security level of 2, 3 or 10.

The Cover
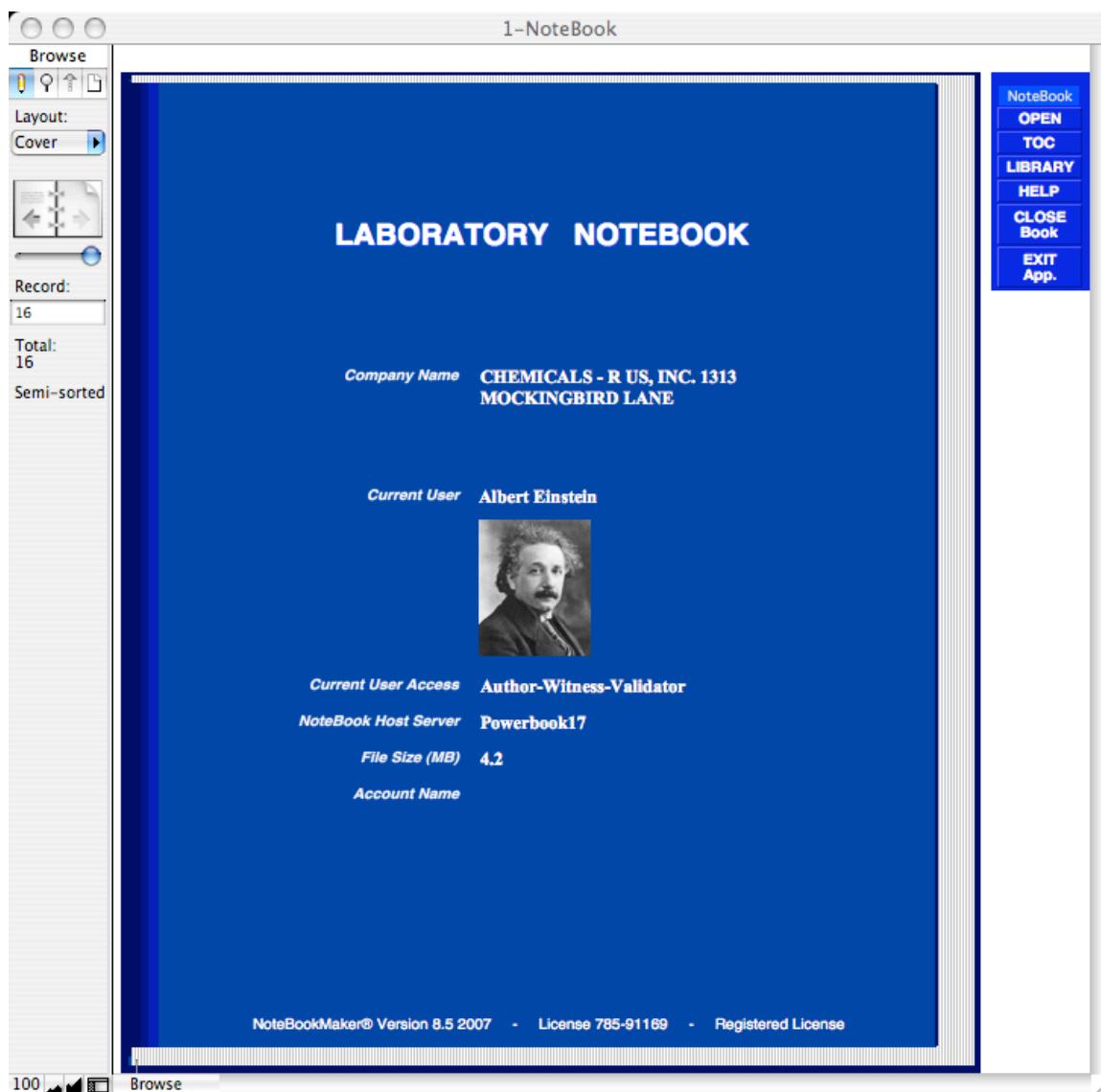
The cover displays the photo identification of the current log in user. In upper right hand corner is a control menu that performs the following functions:

Open will open the notebook to the last page.
TOC opens to the table of contents view.
Library opens the Librarian file.
Help brings up the help information for the cover layout.

Close will close the notebook but keep the application running.

Exit will close all active books and quit the application.

The Page: (TEXT only) no graphics

When you create a new page, you will be prompted to choose between 2 layout styles.
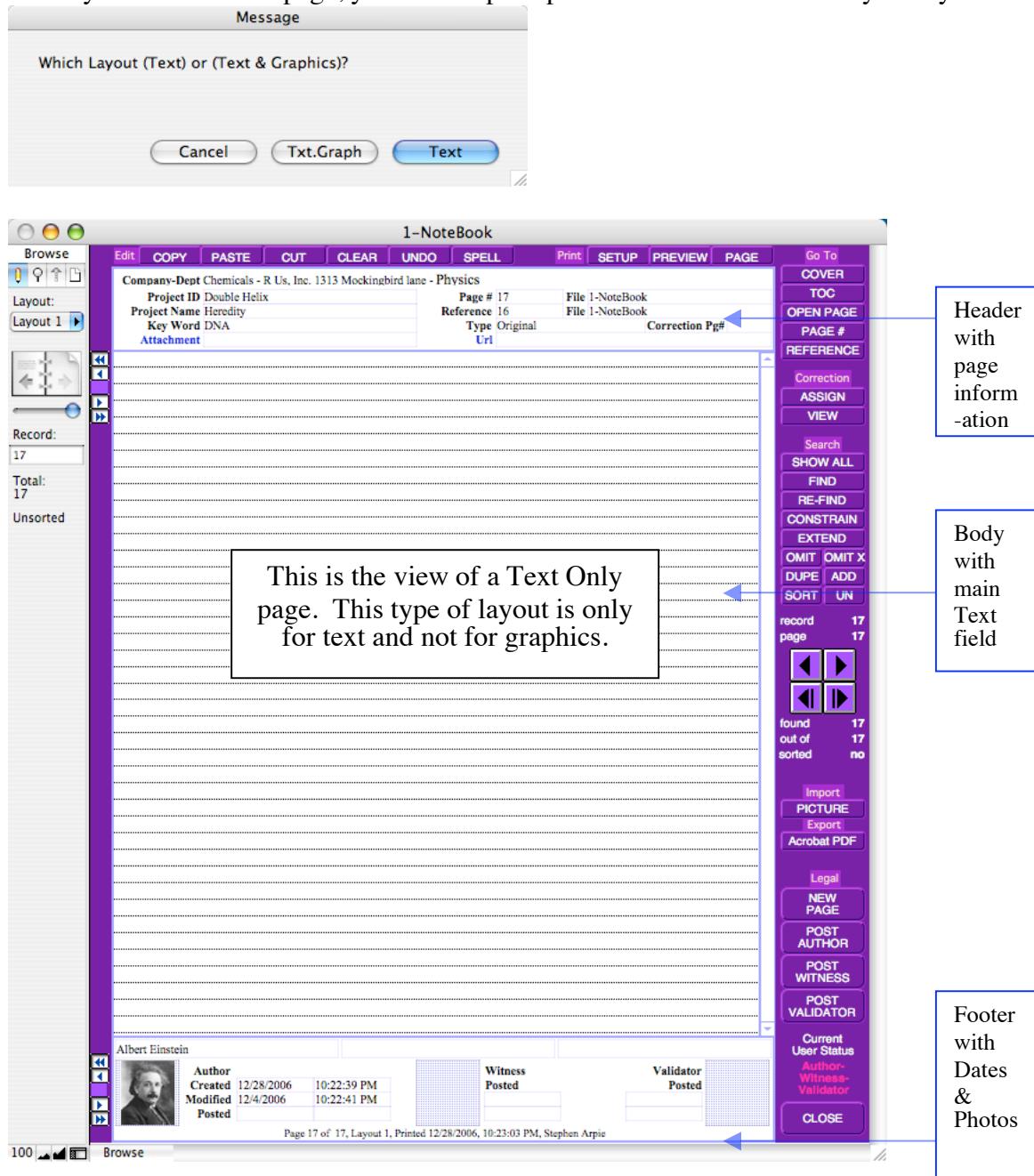
From here you will perform the functions that are listed on the button pallets, such as **Copy**, **Paste**, **Print**, **Go To** navigation, & most importantly, issue **Legal** functions such as **New Page**, **Edit Page**, **Post Author**, **Post Witness**. The security clearance that was set up in the librarian will determine what legal functions that are permitted. There are other constraints as well, such as: an author cannot witness their own page; a witness cannot witness a page that has not been authorized; a "host" cannot authorize or witness any pages, but merely browse. These constraints are essential to legal notebook system. Detailed information can be found in the Help Tabs of each palette.

The Page: (Text and Graphics)

The first layout only involves a body that has one big text area. This text only layout is typically used for free form typing and pasting in text from other programs.   If one wants to preserve the
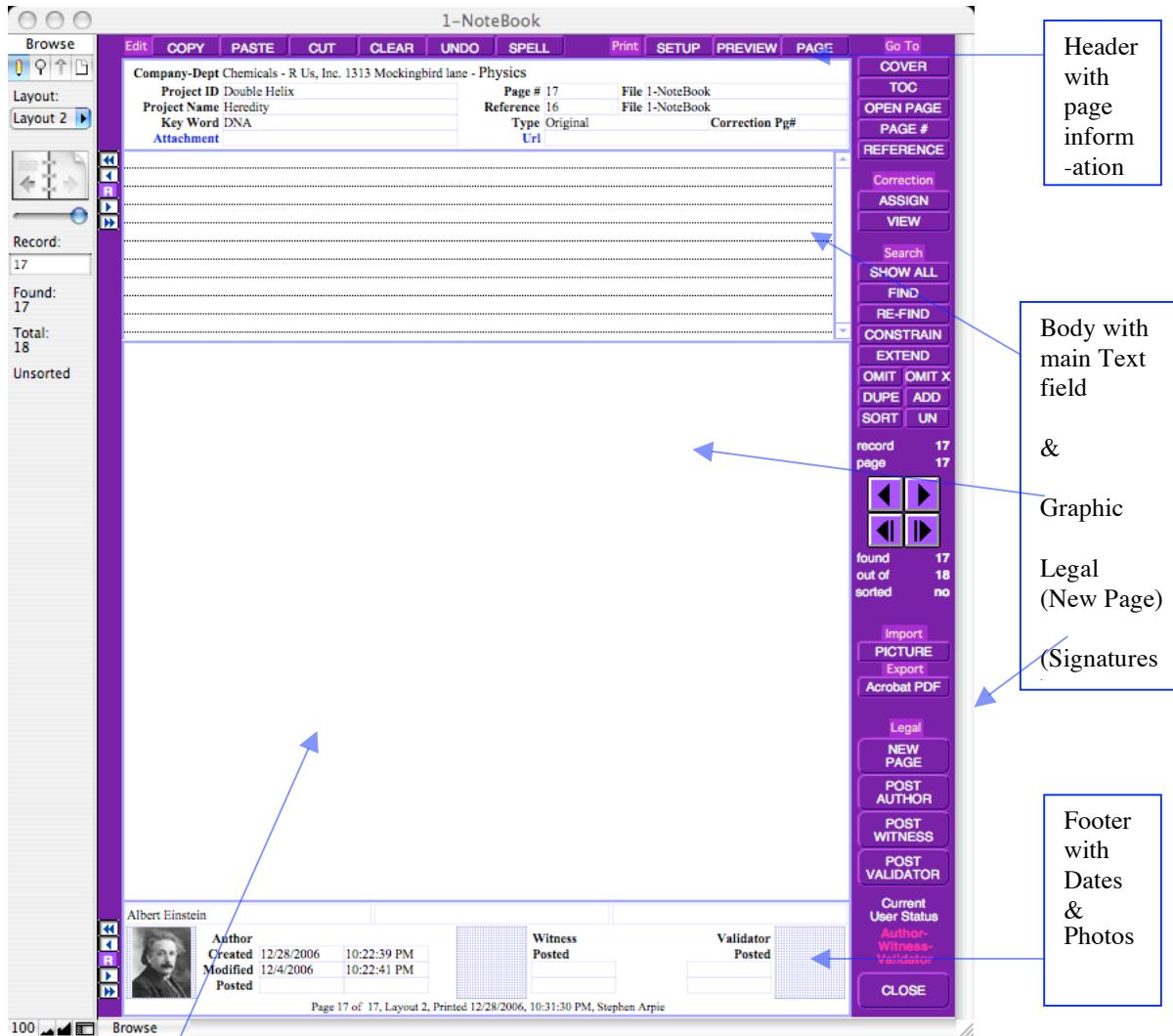
formatting or paste in pictures, then Layout 2 "Text & Graphics" is required. The graphics field above can support many popular formats and thus most popular scientific and graphic programs. Supported formats include: copy/paste, .tiff, .eps, .pdf, .jpg, .gif, and many others. Sound (.aiff, .mp3) and Movie formats are also supported.

Page Headers

As with any page, you should fill out the header fields so you can do proper searches. For example, the Project ID field can be loaded with default values so all your users conform to proper language. Attachment can hold file archives of any type of data.
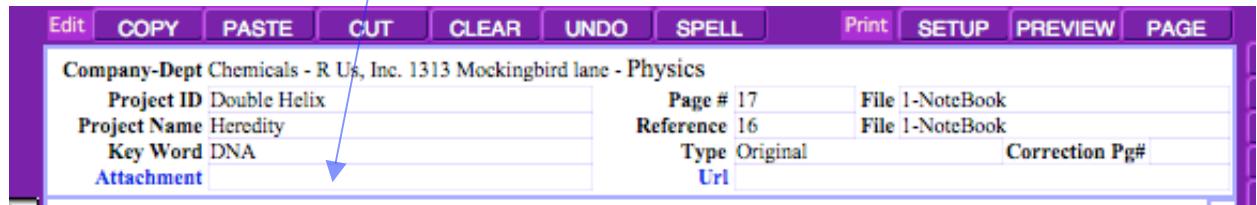
Value List can be Exported and modified in a spreadsheet program and then copied back into any
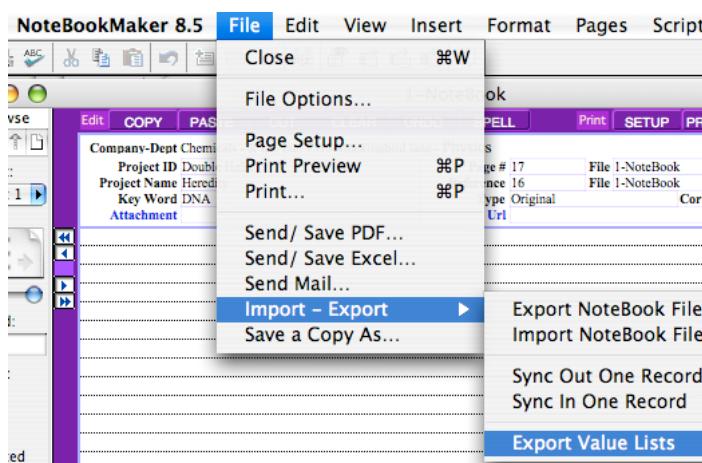
notebook. The last item Export Value Lists is what is used to export not only Project ID, but also Project Name, and Compound Name.

The files created can be found in the parent folder of your 1-NoteBook data file.:
Project Name Value List.tab
Page Type Value List.tab
Project ID Value List.tab

Search Layout

With the header fields in combination with the footer and main body text fields, a user can perform very detailed searches.
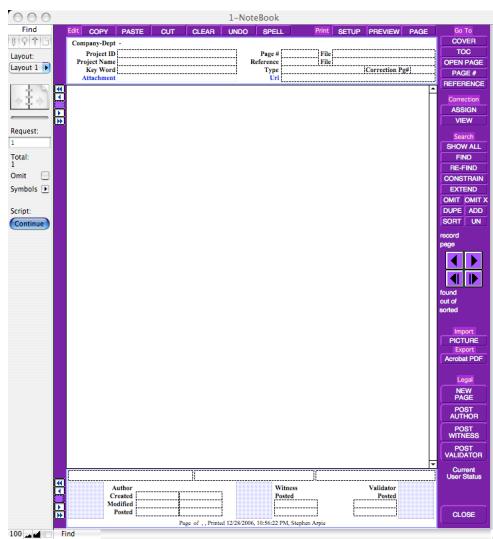
The buttons to the right, under Search tab: Show All Find, Re-Find, and others are convenient ways to conduct searches. Navigational controls are listed under the Go To tab, while the Edit functions are listed at the top left.

Enter your search criteria, create multiple requests, expand, and constrain to get the page records that are of interest.

After you have completed your search, you can print, or report on your found set.

It is important to note that only one book can be searched at one time. If the user wishes to search multiple books then they have two options. The first option is to use merge existing notebooks into one notebook. This can be accomplished by importing multiple books into an empty Template-NoteBook.fp7. You can rename the file before or after the process as long as you have a library card that grants access. Once all the file(s) are imported, then a search will be for all the data. Alternatively, you can export each individual notebook as an Adobe Acrobat Portable Document ".pdf". The network version can export directly to this format. Later, you can import each pdf into a master pdf and use Acrobat's search routines.

Either way, exporting and importing into a master notebook or master pdf are great ways to search on all your organizations data. And, you do not need an IT department to accomplish it. All these functions are straightforward, end user skills.

Table of Contents (TOC)

Each notebook will automatically build a table of contents. The Go To tab provides a great way to perform quick reviews of found data sets. Each field can be sorted to

generate a specific order. The fields displayed are: Project ID, Project Name, Compound Name, Page #, File Name, Author, Posted Date, Witness and Date Created. The reports can be output to any device or electronic format.

An advanced technique involves combining several notebooks into one. The text fields can be exported from each notebook file and imported into a master notebook. This way, all fields can be searched across all notebooks. The TOC will display a master page directory for all your entries.

The export can be .TAB, .XML, or .fp7 formats. The .fp7 is the preferred way to export and import for this feature. It will retain the original formatting and file names.

The Librarian (Detail)

As mentioned in the Setup pages, the Librarian is the place to register your users. Each User shall receive a card with the mandatory fields listed below. The **Go To** tab shall display the following information:
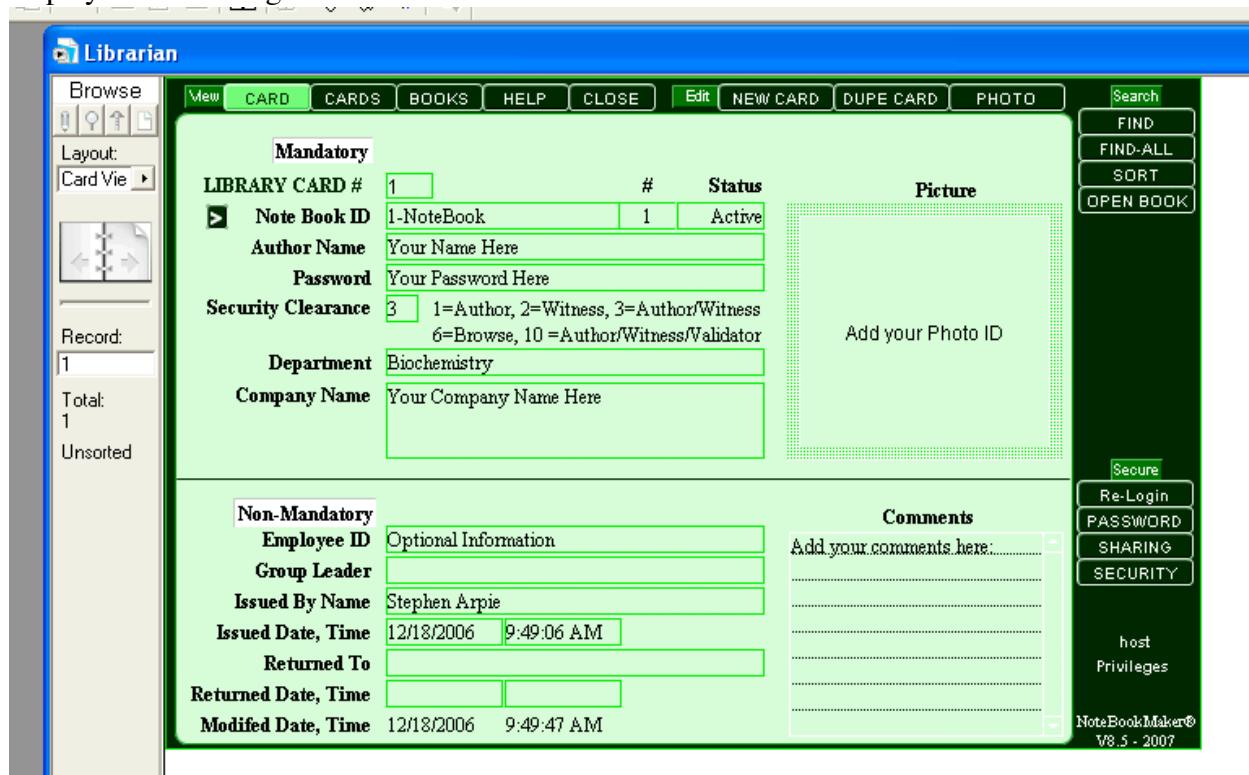
Card View button brings the Librarian Administrator to the card layout. Create and edit cards here. This layout requires Librarian Administration privileges. Normal User privileges will not allow access to the layout. This is because User Names and Passwords are kept here.

Cards View button brings the Librarian Administrator to the table view of found set of cards. Similar to the card view layout, no access is allowed for normal users. This layout is a great way to view all or some of the cards in the Library.

Book View button brings the user to the book view. This is the entry point to the Library. From here you can choose a book to open or Re-Login as the Librarian as the user.

Help button opens the general help layout.

Close will only close the Librarian data file, and not other active files. This will prevent any user from login into any notebook. The Librarian must be open for others to access their notebook.

New Card button creates a new blank card that needs to be filled out before using.

Dupe Card button duplicates the existing library card.

Photo allows the user to directory locate a file that is to be imported in to the user picture. The file format is compatible bmp, cgm, drw, gif, macpaint, pcx, pic, jpg, lotus SLD, tiff, metafile, eps, and epsf. Be sure to select the document preference for Store Compatible Graphics before importing each graphic into your notebook. The preference file will direct the notebook to store cross-platform graphics.

Find places the user in the search mode. Additional criteria commands are available to assist the user in completed a search.
Find-All will show all the card entries in the database.
Sort button allows the user to sort by specified criteria
Open Book button opens the notebook listed in the Note Book ID field. It is designed to provide a fast open routine for systems that contain a large number of notebooks.

button will also open the listed NoteBook.

Re-Login allows the Librarian to log out "leave" the system in a secure mode. Securely type at the prompts Account Name and Password.
Password button provides the identification signature in conjunction with the user's name.
Sharing allows the Host to change the availability of the Librarian to 1 of 3 states: 1. Single User, 2, Multi-User, and 3, Multi-User hidden. Multi-User is the state necessary for networking.
Security button will open the security log layout and allow the Librarian administrator to view the audit trail report.

In **Card View** mode, the found set of records is **navigated** by clicking on the record index in the upper left hand corner of the screen.
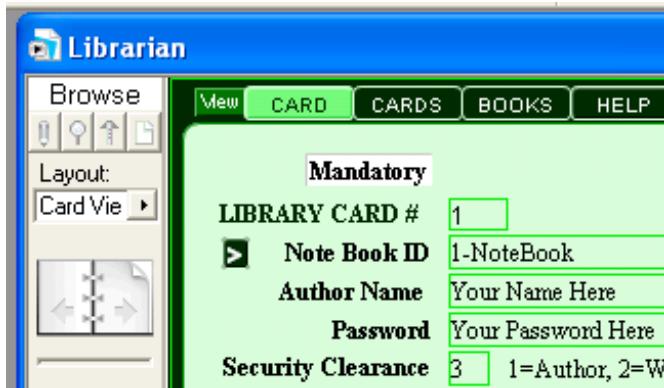
Some additional features are the ability to sort your card set by clicking on the field headers such as: Library Card #, Note Book ID. A complete listing of automation scripts is shown here to the right above.

button will also open the listed NoteBook.

Table View Mode in Detail (Card List for Librarian)

It is obvious that The Librarian is the place to hold all your user information, but there are some other interesting features that system administrators shall appreciate.

A very useful tool built into The Librarian is the **Cards View** mode. It is different than the **Card View** mode primarily because it shows you all the users in a found set. If we issue the **Find All** command before going to table view we will see a complete listing. The Table view can be sorted by clicking on the individual headers, such as Author Name or NoteBook ID. This is extremely helpful when you need to identify who and what someone has access to use or has used. This is a major component of 21CFR Part 11 compliance. System administrators can quickly modify access privileges on the found set by applying replace content command on a particular field. Care must be given before issuing the function. Modifications can't be undone unless they are manually type set.

Book List View Mode in Detail (Book List for users)

Books List mode is the main entry point in the Library.

Here the users can easily find there notebooks and open them. No passwords are viewable from this layout. The Librarian in conjunction with the Security Log provide full security & audit reporting which are key to 21CFR Part 11.

With these tools, you will easily satisfy your auditor's requirements.

The Security Log

From the Card view of the Librarian, the Administrator can readily obtain information about who has opened a notebook and when access has occurred. Also, if there are any failed attempts at login, then they too are recorded by the Security Log. To view this information one simply clicks **Security** button from the Library Card View – Secure scripts palette. Only the Librarian administrator should view this information because it contains all the passwords entered by each user.

The system administrator is shown the cabinet view:
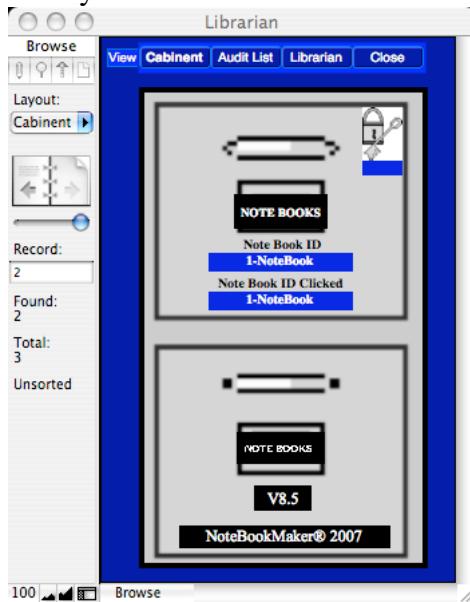
There is a control palette with an **Audit** button that the administrator/host clicks on to gain access to the report.

By clicking the **Find-All** button, a complete report of all activity is generated. Modifying

Dates, names, passwords, and sorting too can customize the report. The audit trail is another key requirement of 21 CFR Part 11 compliance.

During the login process, the Security database opens along with the Librarian and records the information that the user types. The information typed is compared to the information that was set-up in the Librarian by the administrator/host. If the information is a complete match, the

user is presented with their notebook data file (1-NoteBook.fp7 in stand-alone mode, and 1-NoteBook.fm7 in multi-user mode). If the information is not a match, then the user is rejected and has a total of 3 attempts before all the data files are closed.
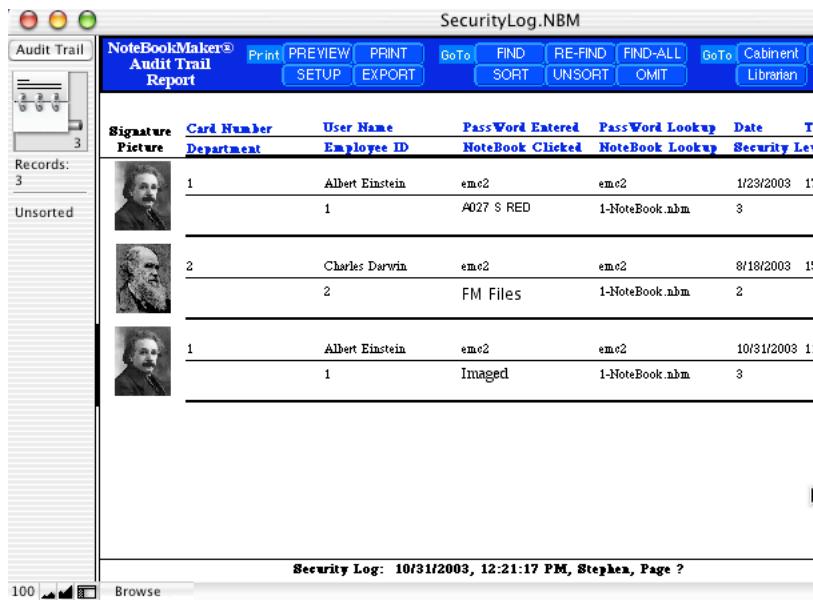
Pasting a Table as Text and as a Graphic.

NoteBookMaker supports Microsoft Excel, Word and PowerPoint files via the clipboard for easy copy-paste functionality.

The advantage of pasting in the table as a graphic element is that the layout is maintained and cannot be changed. This too can be copied out and re-used if required. Any size table can be used in this procedure. Even if the table is very large, it will image out on paper as magazine quality.   Alternately, one could copy/paste sections until the complete table is produced. Use the magnification for on-screen viewing of detailed spreadsheets in **Note**Book**Maker**®.

First, you will click the graphic element and copy;

Next, click back on the notebook page, and issue the paste command.
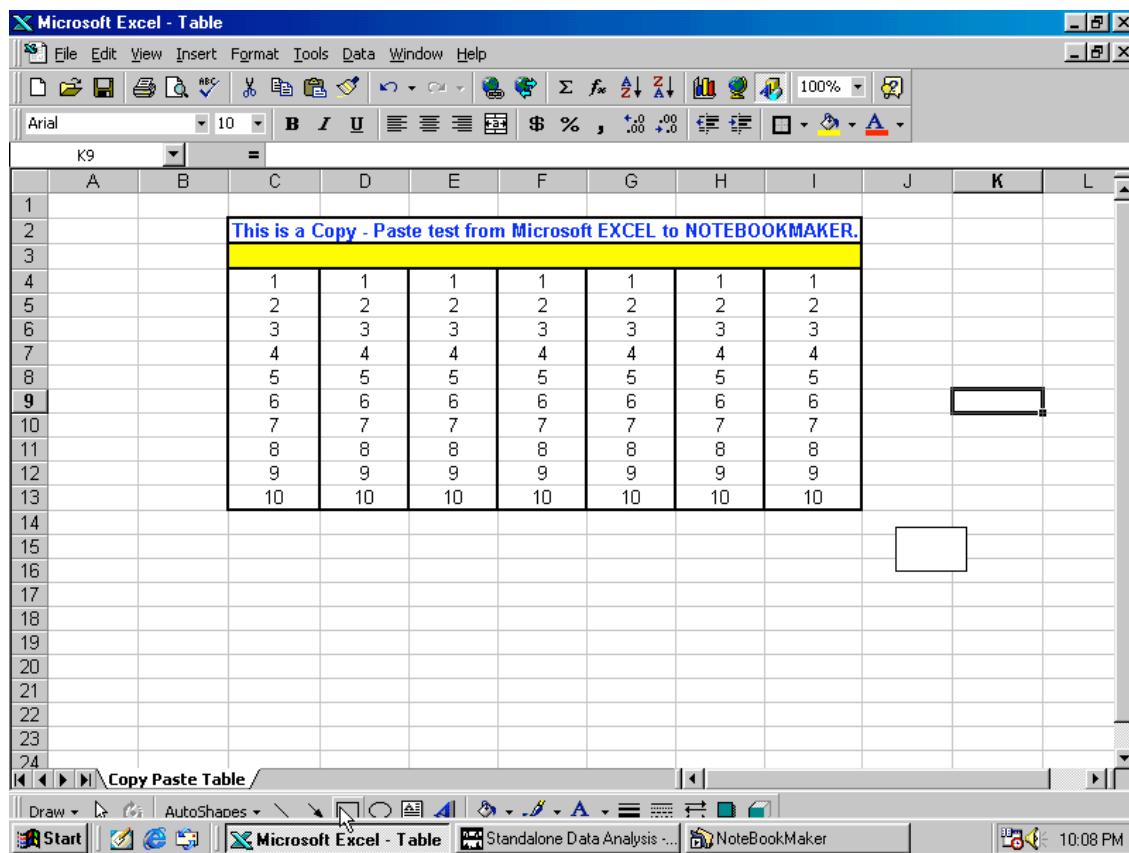
If you want multiple images, such as tables and graphics for the same page, then you will need to shift-click each element, click copy, then bring them over together on the same clip board. The will automatically, reduce to fit and center for proper viewing.

This is how the table looks once you paste it into a graphic/text page.
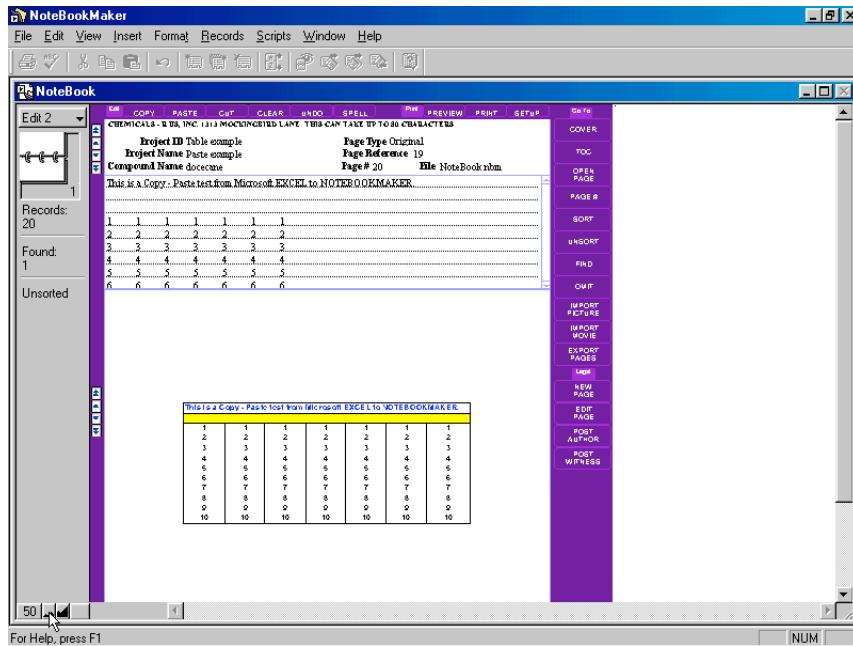
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